JUL 11 2002

K013873

510(k) Summary

Category:	Comments	
Sponsor:	Boston Scientific Corporation/EP Technologies, Inc. 2710 Orchard Parkway San Jose, CA 95134	
Correspondent:	Andrea L. Ruth Senior Associate, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134	
Contact Numbers:	e-mail: Phone: Pager: Fax:	rutha@bsci.com 408.895.3625 888.509.6375 408.895.2202
Device Common Name	Surgical Probe	
Device Proprietary Name	Cobra® Cardiac Surgical Probe	
Device Classification Name	Electrosurgical Unit and Accessories	
Device Classification	Class II, 79 GEI, 21 CFR §878.4400	
Predicate Device	1. Medtronic Cardioblate RF Ablation System, K013392 2. AFx Microwave Flex Ablation Wand System, K003978 3. Wedge Surgical System K870705	
Predicate Device Manufacturer(s)	1. Medtronic 2. AFx 3. Boston Scientific Inc./ Microvasive	
Predicate Device Classification Name(s)	Electrosurgical Units and Accessories	
Predicate Device Classification(s)	Class II, 79 GEI, 21 CFR §878.4400	

Date Summary Was Prepared: July 3, 2002.

Description of the Device:

The Boston Scientific Electrosurgical System is comprised of three components: the Surgical Probe, Electrosurgical Unit (ESU) and Instrument Cable. The Electrosurgical Unit measures temperatures from the thermocouples and uses the temperature measurements to regulate radiofrequency power delivery to the electrodes. The ESU is a software-controlled monopolar high frequency electronic instrument, provided with controls for set temperature, power limit, and number of active electrodes. The ESU has readouts for temperature, time of energy delivery, and delivered power. The ESU operates in a temperature controlled, power limited manner, based on operator settings and temperature feedback provided by thermocouples in the Surgical Probe. Front panel connectors include connections for the Instrument Cable, ESU Remote Cable, and DIP electrodes.

The Surgical Probe is provided in a variety of models, ranging from 2 electrodes to 7 electrodes, with either a malleable or flexible shaft that can be bent to the desired shape, providing improved tissue contact and maneuverability in hard-to-reach areas. The Instrument Cable connects the ESU to the Surgical Probe. Accessories included with the ESU include ESU Remote Cable, Footswitch, Instrument Cable, and mains power cord.

Intended Use:

The Cobra® Cardiac Surgical Probe (Probe) is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The Probe can be used during general surgery to coagulate soft tissues. The Probe may also be used to coagulate blood and soft tissue to produce hemostasis.

Non-clinical Data:

This submission includes only an expanded indication for use, therefore there are no new issues of safety or efficacy, and the previously documented performance reports are still valid and applicable to the system. Specifically, previous non-clinical tests conducted for the Device showed the device met its design-input criteria, and support substantial equivalence. Additional testing showed the device to perform predictably (based on delivery temperature and time) when compared to an equivalent device in an animal model.

Summary:

Based upon the design, materials, function, intended use, comparison with currently marketed devices, and the non-clinical testing performed by Boston Scientific, the Tissue Coagulation System ESU and Accessories has been shown to be substantially equivalent to currently marketed predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2002

Ms. Andrea L. Ruth
Senior Associate, Regulatory Affairs
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, California 95134

Re: K013873
Trade Name: Cobra® Cardiac Electrosurgical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: May 15, 2002
Received: May 17, 2002

Dear Ms. Ruth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K013873

Device Name: Cobra® Cardiac Electrosurgical System

Indication for Use:

The Cobra® Cardiac Surgical Probe (Probe) is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The Probe can be used during general surgery to coagulate soft tissues. The Probe may also be used to coagulate blood and soft tissue to produce hemostasis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013873

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)